



# WBBA

WASHINGTON BIOTECHNOLOGY  
& BIOMEDICAL ASSOCIATION

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Comments re RIN 3245-AK22

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54-62

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April 1, 2005

Gary M. Jackson  
Assistant Administrator for Size Standards  
U.S. Small Business Administration  
409 Third Street, S.W.  
Washington, D.C. 20416

Dear Administrator Jackson,

Thank you for the opportunity to respond to the U.S. Small Business Administration's (SBA's) request for comments on the December 3, 2004 Advance Notice of Proposed Rulemaking (ANPRM) on whether an exclusion from affiliation for venture capital companies (VCC) should be provided in size determinations for eligibility in the Small Business Innovation Research (SBIR) program (69 Fed. Reg. 70197).

The Washington Biotechnology & Biomedical Association (WBBA) joins with BIO, the national industry organization, in urging that the SBA modify SBIR rules to permit both natural and artificial persons, including VCCs, to count toward the 51 percent U.S. ownership and control requirement, ensuring that small biotechnology firms are able to garner both the SBIR grants and the venture capital so critical to moving their innovations to products.

WBBA is a trade associate representing more than 400 biotechnology and medical device companies, research institutions and organizations that are involved in, or support, research and development of medical, agricultural, and environmental products. WBBA's membership represents a cross-section of the industry, from small, research-based startups to mid-sized and large well-established companies. The majority of WBBA members are emerging companies focused on the research and development of new products, goods or services flowing from the life sciences.

Many bioscience companies in the U.S. today got their start through the SBIR program which Congress intended to assist small businesses to commercialize their creations and products. The biotechnology industry is unique in terms of the amount of capital required and the length of time it takes to bring a biotechnology product from conception to the marketplace. The SBIR program provides critical early stage funding for innovative research and development. In addition to grants, many small biotechnology and medical device companies seek venture capital funding early in the development cycle and receive funding from multiple venture capital sources.

Unfortunately, changes in the SBA's interpretation of eligibility standards for SBIR grants now disqualify many start-up companies. Specifically, SBA regulations require that, to be eligible for a grant, a small company must be at least 51 percent owned by one or more "individuals." Current policy considers firms with 51 percent venture capital backing "affiliates" of large joint venture firms. Small start-up firms that have one or more venture capital investors should not be excluded on the basis that they are not majority-owned by "individuals."

WBBA supports the ANPRM's approach for disregarding affiliation under the SBIR program. However, the exclusion from the affiliation rules will have limited practical effect for many small biotechnology firms, because of the fundamental flaw if the regulation requiring direct or indirect 51 percent ownership and control by natural persons remains.

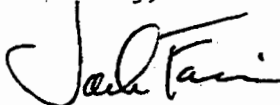
The ANPRM specifically seeks alternative approaches that may assist small business concerns in obtaining and utilizing VCC funding while participating in the SBIR Program. WBBA recommends that SBA adopt a rule that addresses the actual ownership structure of most small biotechnology companies. Specifically, WBBA suggests that the size requirements, 13 C.F.R. § 121.702, be clarified to permit both natural and artificial persons, including VCCs (irrespective of the VCCs' ownership), to count toward the 51 percent U.S. ownership and control requirement. Revising the definition of eligible persons will ensure that small biotechnology companies that are successful in attracting outside VCC investment will remain eligible for SBIR awards. Further, this clarification would reflect Congress' original intent when it established the SBIR program in 1982, and allow federal agencies to continue to support the cutting-edge research being conducted by small biotechnology companies.

WBBA shares the Agency's concern that only genuine small businesses with promising technologies which are not dominated or controlled by other larger business entities receive SBIR awards. Maintaining existing affiliation rules will ensure that SBIR awards go to small businesses that are not majority owned or controlled by large VCC or other corporate entities.


In summary, we submit that continued reliance on a rule essentially requiring 51 percent individual ownership is counterproductive and will actually exclude many deserving small biotechnology businesses from the SBIR program. The simple answer to the current problem is to define the term "individuals" in the present regulation to include both natural and artificial persons. We also request that this change be made retroactive, to allow SBIR awardees whose grants have been revoked under the current interpretation of the regulations, the opportunity to continue to receive funding from this important source.

Please contact us if you have any questions on these comments.

Sincerely,



Jack Faris, Ph.D.  
President



Patti McKinnell Davis  
Director of Government & Public Affairs